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10/650,407	08/27/2003	Ricky W. Purcell	18601 (27839-2523)	6552
45736 7590 05/14/2009 Christopher M. Goff (27839) ARMSTRONG TEASDALE LLP ONE METROPOLITAN SQUARE SUITE 2600 ST. LOUIS, MO 63102				
EXAMINER				
PATEL, TARLA R				
ART UNIT		PAPER NUMBER		
3772				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

USpatents@armstrongteasdale.com

Office Action Summary

Application No.

10/650,407

Applicant(s)

PURCELL, RICKY W.

Examiner

TARLA R. PATEL

Art Unit

3772

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 2/26/09.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-7,9-12 and 14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-7,9-12 and 14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 recites the limitation that "at least one of plurality of portions includes information related to heat that would be generated by the heat patch" and is indefinite since it is vague with respect to the scenario directed to the phrase "would be generated." Specifically, what if the user removed the portion including the information to control the air? No information would be generated.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-2 and 4-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Zhang et al. (5,658,583) in view of Usui (5,879,378) further in view of DeCarlo et al. (6,409,748).

Zhang et al. discloses a heat patch comprising of an enclosure having gas-permeable first layer (26) and second layer (16) bonded together, where in gas permeable first

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layer includes an inner surface and an outer surface (see fig 1), wherein the entire first layer is gas-permeable (column 6 lines 9-20) and a heating composition (28) is located inside the enclosure, which generates heat (column 6 lines 22-28) when a gas is received through first layer. A gas-permeable cover (31) is detachably mounted to said outer surface of first layer (column 6 lines 16-20).

With respect to claim 2, Zhang et al. discloses heat patch include heating composition that comprise iron powder, carbon (reaction promoter), water retaining agent, chloride (salt) and water (column 4 lines 1-4).

With respect to claim 4, Zhang et al. discloses first layer is polyethylene (column 4 lines 5-7).

With respect to claim 7, Zhang et al. discloses a heat patch comprising a heating composition that is capable of generating heat when air is passed through first layer (column 6 lines 22-28).

However, Zhang et al. does not disclose that the gas-permeable first layer is bonded to a perimeter of second layer.

However, Usui teaches an exothermic device and an application pad using the same having first layer (6) is bonded to a perimeter of second layer (5, see figs 1 and 3, see column 23 lines 54-63). at the time of the invention was made, it would have been obvious to one having ordinary skill in the art to modify the first layer of the Zhang et al.'s device to bond to a perimeter of second layer of the device, as taught by Usui to form continuous surface and to better seal the whole device to avoid any exposure to excess air.

Zhang et al. substantially discloses the invention as claimed, further, Zhang et al. discloses a heat patch gas-impermeable cover includes a plurality of portions (31 shown in figure 1 shown to be detachably attached as disclosed in column 11, lines 7-11 that lid adjustable by rotationally or linearly slidable is interpreted as detachable) detachably mounted to outer surface of gas-permeable first layer (column 11, lines 7-11). However, Zhang et al. does not disclose a heat patch having plurality of portions with information related to heat generated by the heat patch when one or more portions is removed from the first layer.

However, DeCarlo et al. discloses a heating pad with removable gel pack further comprising a temperature indicator (24), such as a tape containing an indicating temperature-sensitive liquid crystal substance (column 3 lines 4-9) as disclosed having a tape containing an indicating temperature-sensitive liquid crystal substance is a detachable, since tape by nature are detachable and used as desire. At the time of the invention was made, it would have been obvious to one skilled in the art to modify the heat patch of Zhang et al. to replace at least one of lid/cover with a tape containing an indicating temperature-sensitive liquid crystal substance of the DeCarlo et al.'s heat patch to allow monitoring the use of the heat patch for therapeutic level without damaging the user's skin with higher temperature and an important novel feature of Zhang et al.'s invention to have the capacity to heat and regulate skin temperature to a desired and elevated, narrow range for a sufficient length of time and it is also desirable to be able to vary heating temperature after activation. Further, with respect to limitation of "and wherein at least one of plurality of portions includes information related to heat

generated by the heat patch **when one or more of plurality of portions removed from said gas-permeable first layer**" has been treated as an intended use recitation. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987). Since the limitation have not been positively claimed, it is obvious that the device of Zhang et al., and DeCarlo et al. can be used as required by claim.

With respect to claims 5-6, Zhang et al., and DeCarlo et al. substantially disclose the invention, see rejection to claim 1 above; however, Zhang et al., and DeCarlo et al. do not disclose a heat patch having a second layer and cover each being made of polyethylene film.

However, Usui teaches a heat patch having gas permeable first and second layers made of polyethylene film (column 5 lines 18-24). At the time of the invention was made, it would have been obvious to one skilled in the art to modify the heat patch of Zhang et al. and DeCarlo et al. to have polyethylene film second layers to have better flow of air to the composition and more heat to the skin being treated of the user, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

It would have also been obvious to one having ordinary skill in the art at the time the invention was made to make the cover of Zhang et al. and DeCarlo et al. with polyethylene film as taught by Usui to have better air permeability through it, since it has

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been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

5. Claims 9-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Zhang et al. (5,658,583), Usui (5,879,378) and DeCarlo et al. further in view of Kuratomi et al. (4,747,841).

Zhang et al. and Usui substantially disclose the invention, see rejection to claims 1-2 and 4-7 above; however Zhang et al. does not specifically disclose a heat patch having a heating composition that maintains the temperature of second layer about 38°C-40°C, or 40°C-42°C, or 42°C-45°C when composition is exposed to air.

However Kuratomi discloses a heat patch it maintains the temperature of second layer to be at between or about 40°C-45°C when composition is exposed to air (column 2 lines 62-64) by removing sealing plate (14). The disclosed range of 40-45C meets the claim range limitation of claim 9-11, since it overlaps in at least part of each range. At the time of the invention was made, it would have been obvious to one skilled in the art to modify the heat patch of Zhang et al. to use Kuratomi's teaching of maintaining the temperature of second layer about 40-45 degree centigrade when the membrane is exposed to air (gas) to be able to reach desirable temperature to allow more customize treatment of individual by the heat patch.

With respect to claim 12, Zhang et al. discloses plurality of portions (column 11, lines 7-12). Zhang et al. further disclose a few small pieces of tape (31) to peel off and cover

opening (26) to regulate the airflow is equivalent to required plurality of portions including strips.

6. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Zhang et al., Usui and DeCarlo et al., further in view of Christy et al. (5,692,238).

Zhang et al., Usui and DeCarlo et al. substantially disclose the invention, please see rejection to claims 1-2 and 4-7; however Zhang et al., Usui and DeCarlo et al. do not disclose a heat patch having at least some of plurality of portions that are different colors, where the different colors give information related to heat generated by the patch, when one or more portions are removed from the first layer.

However, Christy et al. teaches a microwave-heatable exercise putty in a container with temperature indicator comprising affixed to the inside of the bottom wall is a heat sensitive strip which includes a thermo chromic semiconductor material which varies in transparency and color in response to various temperature levels to which material is exposed (column 3 lines 7-12, as disclosed affixed to bottom wall is not specifically disclosed by which means is broadly interpreted by the examiner as being any means and would be detachable). At the time of the invention was made, it would have been obvious to one skilled in the art to replace at least some of strips of the heat patch of Zhang et al., Usui and DeCarlo et al. with strip which includes a thermo chromic semiconductor material which varies in transparency and color in response to various temperature levels, which is taught by Watson, Jr. to regulate the temperature of heat

pack.

Response to Arguments

7. Applicant's arguments filed 2/26/09 have been fully considered but they are not persuasive.

8. With respect to applicant argument to 112 rejections that the information related to heat generated by the heat patch is adequately defined and clear in light of the specification, to these arguments the examiner respectfully disagrees. As the claim limitations are read in light of specification, however, one does not read disclosed information from the specification into the claims as a limitation. As the claim recites the limitations that "at least one of plurality of portions includes information related to heat that would be generated by the heat patch" is indefinite as to what information could be released if the user removed the same portion including the information to control the air. Further, if you had only one portion and if user removed that portion, than what information one would have and if any? Further, if the user decide to not remove any portion, what information it would have then. since, the claim limitations recites that the "at least one of plurality of portions includes information related to heat that would be generated by the heat patch when one or more of said plurality of portions is removed from said gas-permeable first layer", the heat would still be generated, even if still none of portion would be removed by the user, since the whole first layer is made of gas-permeable material.

9. With respect to applicant argument that Zhang et al. does not include a plurality of portions as is recited in claim 1, rather the cover in Zhang et al. is a single cover that includes substantially non-air permeable area and opening with desired permeability to air, wherein openings may be covered during use by a piece of tape of the patch, to that the examiner respectfully disagrees. The examiner's position is that the opening with desired permeability to air is still would provide the same structure and resulting functionality as the claimed invention of exposing the heating composition with air for generating heat; further use of strips 31 over the openings would regulate the temperature generated by the composition and said strips are detachably attached as described above in rejection to claim 1. Please see rejection above to claim 1. Further as set forth above, Zhang et al. teaches that it is an important novel feature of Zhang et al.'s invention to have the capacity to heat and regulate skin temperature to a desired and elevated, narrow range for a sufficient length of time and it is also desirable to be able to vary the heating temperature after activation. The examiner's position is that it is suggested of Zhang et al. to regulate the temperature by use of strips 31.

10. With respect to applicant's arguments that the cover or structure (22) of Zhang et al. does not include a plurality of portions, the cover of Zhang et al. merely has the capability to accept these pieces of tape during use of the patch in order to regulate the temperature of the patch; as the plurality of portions of the instant application are detachably placed on the heat patch before use and can be removed as desired, to these arguments the examiner respectfully disagrees. The examiner's position is that the pieced of tape cover the opening to provide desired permeability to air is still would

provide the same functionality as the claimed invention of exposing the heating composition with air for generating heat and further use of strips 31 over the opening would regulate the temperature generated by the composition and are detachably attached as described above in rejection to claim 1. further, it is well known that the tapes can be detachably attached to any surface, therefore the tapes of Zhang et al. can be used as desired, where there is reason to believe that a functional limitation asserted to be critical to establishing novelty in the claimed subject matter may, in fact, be an inherent characteristic of the prior art, applicant may be required to prove that the subject matter shown in the prior art does not possess the characteristic relied upon. In *re Spada*, 911 F. 2d 705, 15 USPQ2d 1655 (Fed. Cir. 1990); In *re King*, 801 F. 2d 1324, 1327, 231 USPQ 136, 138 (Fed. Cir. 1986); In *re Ludtke*, 441 F. 2d 660, 664, 169 USPQ 563, 566 (CCPA 1971).

Further, With respect to argument that the plurality of portion of instant application are detachably placed on the heat patch before use and can be removed as desire, to that the examiner would like to point out that the applicant does not claim that the plurality of portion are detachably placed on the heat patch.

11. With respect to applicant arguments to Usui, the examiner points out that the Usui is only used for teaching of bonding of first layer and second layer at the perimeter.

12. Further, applicant's argument to 35 USC 103 rejection to the Zhang et al, Usui and DeCarlo et al. combination does not articulate TSM approach to obviousness, to that the examiner respectfully disagrees. All the reference are same analogous art and taught to be used for patch for body use for temperature. All the references are used to

place over body to control temperature to the body; therefore it would have been obvious to use these references to combine the teaching and to provide the unexpected results.

13. Applicant further argues that Zhang et al. does not disclose a cover formed of a plurality of portions detachably mounted to a gas-permeable layer to accomplish the result as required in instant application claim 1 and where removable portions are included within the cover and are removed to expose a portion of the gas-permeable first layer, to that the examiner respectfully disagrees. The argument is more specific or narrower than what is claimed. Further, the examiner would like to point out that the originally filed specification and drawing figure does not support the argument that the a cover is formed of a plurality of portions, however, the cover is portions as shown in figures 3-4 of elected Species and portion are not included within the cover, they are cover as shown and disclosed in originally filed specification.

14. Applicant argues that the Usui and DeCarlo references does not discloses a gas permeable cover that includes a plurality of portions detachably mounted to the outer surface of the gas-permeable first layer and further including information related to heat that would be generated by the heat patch and the indicator in DeCarlo et al. is not meant to be removed, to that the examiner respectfully disagrees. The Usui reference is only used for teaching of bonding of first layer and second layer at the perimeter. Further, the DeCarlo reference is only used for teaching of tape containing an indicating temperature-sensitive liquid crystal substance as described in rejection above. It is position of the examiner that the tape as disclosed in DeCarlo by nature is removable as

all tapes are. The examiner asserts that the opening with desired permeability to air is still would provide the same functionality as the claimed invention of exposing the heating composition with air for generating heat and further use of strips 31 over the opening would regulate the temperature generated by the composition and are detachably attached as described above in rejection to claim 1.

15. Applicant also argues that there is no reason to combine the DeCarlo et al. with Zhang et al. and Usui, that the DeCarlo et al. reference is directed to a completely different mechanism of heating from that of Zhang et al. and the Usui requires an exothermic reaction to generate heat, but rather, DeCarlo et al. teaches a heat-retentive gel, to these arguments the examiner respectfully disagrees. Usui and DeCarlo et al. are not relied upon material of heat generated pack/patch, rather the, Usui reference is relied upon for teaching of bonding of first layer and second layer at the perimeter and the DeCarlo reference is only relied upon for teaching of tape containing an indicating temperature-sensitive liquid crystal substance as described in rejection above. Further, they are related in examiner's opinion to be analogous art.

16. With respect to applicant's argument that the Kuratomi et al. does not disclose gas permeable cover that includes a plurality of portions detachably mounted to the outer surface of the gas-permeable first layer and includes information related to heat that would be generated by the heat patch, the examiner relied upon the Kuratomi et al. reference as a teaching of range of temperature and not for gas permeable cover with a plurality of portions detachably mounted to the outer surface of the gas-permeable first

layer and includes information related to heat that would be generated by the heat patch.

17. Applicant also argues regarding claim 14 that Christy et al. does not disclose gas permeable cover includes a plurality of portions detachably mounted to the outer surface of the gas-permeable first layer and includes information related to heat that would be generated by the heat patch. Christy et al. is relied upon for teaching of color in response to various temperature, not for plurality of portions detachably mounted to the outer surface of the gas-permeable first layer and includes information related to heat that would be generated by the heat patch.

Conclusion

18. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Kunamoto (2006/0276863) discloses a warming tool with color change when there is change in the temperature of the pad.

19. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to TARLA R. PATEL whose telephone number is (571)272-3143. The examiner can normally be reached on M-T 6-3.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on 571-272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Tarla R Patel/
Examiner, Art Unit 3772

/Patricia Bianco/
Supervisory Patent Examiner, Art Unit 3772